SEP - 6 2007

Coeur Medical, a division of Coeur, Inc.
Disposable High Pressure Injection Lines with and without Rotating Adapters

510(k) Summary

1. **Submitter:**

Name:	*Coeur Medical, a division of Coeur, Inc.*
Address:	*209 Creekside Drive*
	Washington, NC 27889
Phone:	*(615) 547-7923 (Corporate Office)*
Fax:	*(615) 547-7937 (Corporate Fax)*
Contact:	*Debra F. Manning, VP, Q & RA*
Date:	April *27, 2007*

2. **Device:**

Trade/Proprietary Name:	*Disposable High Pressure Injection Lines with and without Rotating Adapters*
Common/Usual Name:	*High Pressure Lines*
Classification Name:	*Diagnostic Intravascular Catheter* (21 CFR 870.1200, Product Code DQO)

3. **Legally Marketed Devices to which Substantial Equivalence is claimed:**

Medrad High Pressure Connecting Tube (K810924) - Medrad

Advance Pressure Monitor/High Pressure Lines (K911884) – Advance Medical Designs, Inc.

Ultra High Pressure Injector Lines (K023591) – DeRoyal Industries, Inc.

flexcil® Contrast Injection Lines (K822100) – NAMIC

High Pressure Lines (K963749) – Maxxim Medical, Inc.

4. Device Description:
The Disposable High Pressure Injection Lines with and without Rotating Adapters are a combination of connectors and tubing bonded together for injection of radiopaque dye, saline, or other diagnostic fluids during a coronary angiography procedure. The device is designed, like other legally marketed devices, for one end to connect to the fluid source (such as an angiographic syringe) and the other end to connect to the catheter. The contrast, saline, or other diagnostic fluid is then injected from the syringe, through the high pressure line, into the catheter. The materials and properties of the device are tabled in Item 6, below.

5. **Intended Use of Device:** The Disposable High Pressure Injection Line with and without Rotating Adapter is for use during coronary angiography procedures as a connecting line for the injection of radiopaque dye, saline, or other diagnostic fluids. As the table in Item 6 demonstrates, this is consistent with other legally marketed devices.

6. **Summary of Technological Characteristics As Compared to Predicate Devices:**

Technological Characteristics	Proposed Device	Other Legally Marketed Devices	Rationale for Applicable Differences
Intended Use	For use during coronary angiography procedures as a connecting line for the injection of radiopaque dye, saline, or other diagnostic fluids.	Medrad: To connect an angiographic catheter for needle to an automatic power injector. De Royal: For use during coronary angiography procedures and connecting line for the injection of radiopaque dye or saline. NAMIC: Intended to be used in the delivery of contrast media.	NA: There are no significant differences in the intended uses.
Connector Tube	Multiple lengths of braided or unbraided, flexible, clear or tinted, plastic polymers	Multiple lengths, plastic polymers, PVC, braided and unbraided, varying levels of flexibility	The same basic materials will be used in the proposed devices as are used in legally marketed devices. Coeur intends to offer a more flexible device that meets the needs of the high pressure market.
Sterility	Sterile and Non-Sterile	Same	NA
Sterilization Method (For Sterile Product)	EtO	Same	NA
Components	Combinations of male and female luers (including rotating male luers), with and without dust caps	Same	NA
Packaging of Sterile Product	Sealed Tyvek-lidded package or included as component in trays or kits. Products may be wrapped with a band to facilitate packaging.	Same	NA
Pressure Rating	500 to 1200psi	Same	NA

If Substantial Equivalence was based on an Assessment of Performance Data, the following information is also provided:

1. Nonclinical Tests Submitted: *Verification of functional performance has been performed. As 1200psi is the greatest pressure for which the device is developed, pressure testing was conducted at 1200psi to verify acceptable performance of the "worst case" challenge. The Coeur sterilization cycle is able to sterilize the proposed device with an SAL of 10^{-6}, based on a comparison to products tested for inclusion into the Coeur cycle. (A product analysis, compliant with AAMI/ANS/ISO 11135/EN 550, will be performed and appropriate actions will be taken accordingly.)*

2. Clinical Tests Submitted: *NA*

3. Conclusions Drawn from Nonclinical and Clinical Tests Submitted: *The primary difference between the proposed Coeur devices and other legally marketed predicate devices is that Coeur, who has experience in the production of tubing extension products and has the facilities and equipment for assembly of the proposed devices, will assemble the components to make the proposed devices which will be sterilized in Coeur's sterilization cycle. Coeur intends to offer a variety of high pressure lines, including a more flexible device that meets the needs of the high pressure market. The results of the testing verify the proposed devices are suitable for their intended use.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Coeur, Inc.
c/o Ms. Debra F. Manning
V.P. of Quality and Regulatory Affairs
704 Cadet Court
Lebanon, TN 370787

Re: K071196
Trade/Device Name: Disposable High Pressure Injection Lines with and without Rotating Adapters
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter, Intravascular, Diagnostic
Regulatory Class: Class II
Product Code: DQO
Dated: August 10, 2007
Received: August 13, 2007

Dear Ms. Manning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071196

Device Name: Coeur, Inc. Disposable High Pressure Injection Lines with and without Rotating Adapters

Indications For Use:

for use during coronary angiography procedures as a connecting line for the injection of radiopaque dye, saline or other diagnostic fluids.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071196